REMARKS

Claims 35-39 are pending in the present application. The Examiner has rejected Claims 35-39 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled.

The Claimed Invention Meets the Requirements of 35 U.S.C. §112, first paragraph.

Claims 35-39 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled. In particular, the Examiner asserts that the specification fails to provide any predictable use for the claimed compositions. Applicant respectfully disagrees.

The Examiner acknowledges that the specification provides sufficient guidance with respect to the production of multivalent compositions that are the subject matter of these claims. The Examiner's sole basis for alleging lack of enablement is the allegation that the specification has not provided any predictable use for the claimed method (Office Action, page 3). Applicant respectfully disagrees. As the Examiner noted, the specification clearly discloses that the use of the multivalent compositions is as an antigenic composition to elicit an immune response (Office Action, page 3). At the time of filing of the present application, it was known to treat B-cell lymphoma by administering a monovalent idiotype protein (*e.g.*, an isolated B-cell surface antibody) corresponding to the most abundant antibody molecule expressed on the surface of the B-cell tumor (Specification, page 51, line 27 to page 52, line 1). It was also established in the art that an isolated (monovalent) B-cell surface antibody (from a tumor cell) could be used to induce an immune response (*i.e.*, used as a vaccine) for the treatment of the B-cell tumor (see, *e.g.*, Specification at page 89, lines 1-7). The present invention provides novel methods for producing tumor-associated proteins such as B-cell tumor cell surface antibodies recombinantly, such that they can be made quickly, and such that they are multivalent – *i.e.*, they represent not just the most abundant antibody expressed on the surface of the tumor cells, but also represent variants cause by somatic mutation (see, *e.g.*, the specification at page 54 line 22 to page 55, line 5). The Examiner has provided **no** evidence that contravenes the knowledge in the art regarding the use of B-cell tumor surface antigens in tumor therapy, or that suggests that use of the multivalent compositions of B-cell surface proteins produced by the methods of the present invention to induce an immune response is unpredictable.

The Examiner cites Raychaudhuri (U.S. Patent 5,270,202) and Wu (U.S. Patent No.

6,632,431) in support of his argument that the production of internal image anti-idiotype antibodies is unpredictable. However, the present claims *do no relate to the production of internal image-anti-idiotype antibodies*. According to Raychaudhuri , the process of generating internal image anti-idiotypes antibodies involves 1) making an antibody (Ab1) against an antigen; 2) making anti-idiotypic antibodies (Ab2s) against Ab1; and 3) screening the Ab2s for idiotypes that mimic the initial antigen. (See, *e.g.*, 5,270,202, col. 2, line 65 to col 3. line 5). The successful process requires that the internal image anti-idiotype antibodies mimic the initial antigen (*e.g.*, in its ability to stimulate an immune response). Moreover, the initial antigen need not be an immunoglobulin molecule, so that the internal image anti-idiotype antibodies discussed by Raychaudhuri encompass Ab2s that must mimic non-antibody molecules.

The methods of the present invention are not directed at the production of the internal image anti-idiotype antibodies of Raychaudhuri and do not comprise the steps recited above. In particular, the claimed methods do not comprise the steps of making an antibody (Ab1) against an antigen, making anti-idiotypic antibodies (Ab2s) against Ab1, and screening the Ab2s for idiotypes that mimic the initial antigen. As the teachings in the Raychaudhuri and Wu references regarding the unpredictability of the generation of internal image anti-idiotype antibodies are not related the methods of the present invention, they certainly do not provide any evidence that use of the multivalent compositions of B-cell surface proteins produced by the methods of the present invention to induce an immune response is unpredictable.

Chatterjee (U.S. Patent No. 6,235,280) is similarly unrelated to the present invention. The Examiner cites Chatterjee in support of the contention that not all anti-idiotype antibodies can be used in regimens against tumors. In the passage cited by the Examiner (Office Action, page 4, citing col 2, lines 39-53), Chatterjee is discussing the challenges of using anti-idiotype antibodies *as mimics of a primary tumor-associated antigen* (*i.e.*, using them in the fachion of the internal image anti-idiotype antibodies of Raychaudhuri) as for use in eliciting an immune response against that antigen (see Chatterjee, col 2, lines 8-53, taken together). In contrast, the present invention describes methods of recombinantly producing tumor-associated antigens from B-cell tumor cells, not methods of producing antibody mimics of these antigens by raising antibodies against them, then raising anti-idiotype antibodies against those. The teachings in Chatterjee are unrelated to the present invention and do not provide any evidence of

unpredictability of the methods of the present invention. In particular, Chatterjee provides no evidence that use of the multivalent compositions of B-cell surface proteins produced by the methods of the present invention to induce an immune response is unpredictable.

Applicants submit that claimed invention satisfies the requirements of 35 U.S.C. §112, first paragraph for the reasons recited above, and respectfully requests that this rejection be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all reasons for rejection have been addressed and that Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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